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These search terms have been highlighted: **bio psa**

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## Adhesives

To assure their safe use in pharmaceutical drug delivery and wound applications, pressure sensitive adhesive products are manufactured, packaged and tested at the Healthcare Industries Manufacturing Site utilizing principles of cGMP regulations for Active Pharmaceutical Ingredients (APIs).

### Regulatory Status

Tested for USP Class V Ex  
FDA Material Application  
European Technical  
and FDA Drug Master File

### Pressure Sensitive Adhesives

Description	Typical Applications	
Solvent-based hot melt adhesive non-crosslinking pressure sensitive adhesive formulations	* Adhesive of dressings prosthetics and other devices to the body	
Amorphous adhesive in solvent, custom formulation adhesive solvent selection	* Skin adhesion of transdermal drug delivery systems specifically designed for compartments with limited adhesion areas	<i>Dow Corning</i> 3100 Series Adhesive
Custom adhesive formulations no solvent	* Skin adhesion of transdermal drug delivery systems to the body	<i>Dow Corning</i> 3100 Series Adhesive
Solventless adhesive formulation with an adhesive back customization	* Skin adhesion of transdermal drug delivery systems to the body	<i>Dow Corning</i> 3100 Series Hot Melt Adhesive

### Customizable Pressure Sensitive Adhesives for Transdermal Delivery Systems

<i>BIO-PSA</i> 3143 Series
<i>BIO-PSA</i> 3142 Series
<i>BIO-PSA</i> 3141 Series

Dow Corning medical adhesive products have been developed to meet the needs of the medical industry.

Description	Typical Applications	Regulatory Status
Two-part, platinum-catalyzed adhesive, e. g. for severe crusts	* Clear and soft skin adhesive for wound dressing and pharmaceutical topical or transdermal applications	Food Contact

1e  
non-preserved skin

### Soft Skin Adhesive

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# Product Information

## Healthcare Industries

DOW CORNING

### **Dow Corning® MD7-4502 Silicone Adhesive**

### **Dow Corning® MD7-4602 Silicone Adhesive**

#### **FEATURES**

- Pressure sensitive adhesive
- Nonsensitizing
- Nonirritating

#### **Nonsensitizing, pressure sensitive adhesives**

#### **APPLICATIONS**

*Dow Corning® MD7-4502 and MD7-4602 Silicone Adhesives may be used where a nonsensitizing adhesive is needed to adhere dressings, prosthetic and other metal or plastic devices to the body. Known applications include:*

- Adhering ileostomy and colostomy appliances to the skin
- Attaching appliances to the skin for patient monitoring
- Affixing surgical dressings and pads to the skin
- Adhering external prosthetic devices
- Hairpiece adhesion

#### **TYPICAL PROPERTIES**

Specification Writers: Please contact your local Dow Corning sales office or your Global Dow Corning Connection before writing specifications on this product.

<b>Method</b>	<b>Test</b>	<b>Unit</b>	<b>Result</b>	
			<b>MD7-4502</b>	<b>MD7-4602</b>
CTM 0086	Solid Content	percent	65	60
	Nominal Tack Value		Medium	High
	Peel Adhesion	g/cm	700	500
	Shear	kg 6.25 cm <sup>2</sup>	16	15
CTM 0006	Flash Point	°C (°F)	-4.4 (24.1)	-4.4 (24.1)
	Solvent		Ethyl Acetate	Ethyl Acetate
CTM 0001A	Specific Gravity at 25 °C (77 °F)		1.02	1.02
CTM 0050	Viscosity	mPa·s	2500	3000
	Rheology Eta at 0.01 rad sec at 30 °C (86 °F)	P	5 x 10 <sup>-7</sup>	5 x 10 <sup>-7</sup>

CTMs (Corporate Test Methods) correspond to standard ASTM tests in most instances. Copies of CTMs are available upon request.

#### **DESCRIPTION**

*Dow Corning MD7-4502 and MD7-4602 Silicone Adhesives are nonsensitizing pressure sensitive adhesives specifically designed for adhering medical devices to the body. Specific advantages of these products include:*

- Adhesion to many surfaces
- Retained adhesive properties in the presence of moisture or perspiration, under normal temperature variations
- Excellent permeability to moisture and gasses
- Long lasting, non-gumming and non-peeling characteristics

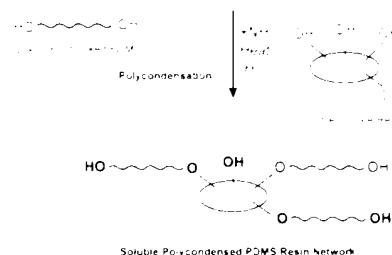
#### **IMPORTANT NOTE**

The purchaser should understand the limited warranty described herein and thoroughly test products made in part or otherwise with *Dow Corning MD7-4502 Silicone Adhesive* or *Dow Corning MD7-4602 Silicone Adhesive* to determine the acceptability of the product's performance in a specific application.

#### **SYNTHESIS AND STRUCTURE**

*Dow Corning MD7-4502 and MD7-4602 Silicone Adhesives are products of the condensation of a silanol*

endblocked polydimethylsiloxane (PDMS) with a silicate resin as shown:



## BIOCOMPATIBILITY

Biocompatibility tests, which meet or exceed current USP Class VI Plastics Tests, and which have been performed on the solids found in *Dow Corning* MD7-4502 and MD7-4602 Silicone Adhesives, are shown in Table I.

Adhesive solids were further evaluated for acute effects using direct application of adhesive and adhesive solids. The material did not produce skin irritation when applied to the skin of albino rabbits.

A cumulative skin irritation test in humans was also performed with *Dow Corning* MD7-4502 and MD7-4602 Silicone Adhesives. The results

of the test indicated that the product was not a primary skin irritant. There was also no evidence that the product possessed skin fatiguing properties. A separate human repeat insult patch test indicated that the solids did not cause skin sensitization.

Every production lot of adhesive is tested for the absence of cytopathic effects using a tissue cell culture test (direct contact method).

## MANUFACTURING ENVIRONMENT

*Dow Corning* MD7-4502 and MD7-4602 Silicone Adhesives are manufactured, tested and packaged under strict quality control guidelines at the Healthcare Industries Materials Site (HIMS). The HIMS (Hemlock, Mich.) is dedicated to the production of silicone materials for healthcare applications. It is registered with the U. S. Food and Drug Administration (FDA) as a drug establishment (CFN 1816403). The site quality system for active pharmaceutical ingredients (APIs) is in compliance with current Good Manufacturing Practices for Bulk Pharmaceutical Products. The site is also ISO registered by BSI.

**Table I: Biocompatibility**

Test	Results
Cytotoxicity ( <i>in-vitro</i> )	Non-cytopathic effects
Irritation	Nonirritating
Sensitization	Nonsensitizing
Subacute Toxicity USP Class V Extractables	No difference between extract and control
90-Day Implant	Equivalent response between control and test material

A cottonseed oil extract tested positive in one test, but in a separate test, no reaction was detected.

## HOW TO USE

### How to Apply

Apply the liquid adhesive to clean substrates and allow the solvent to *fully evaporate* before contact with the skin is made.

### Removal

From the skin: When removing *Dow Corning* MD7-4502 or MD7-4602 Silicone Adhesives from the skin, either *Dow Corning* Q7-9180 Silicone Fluid (1 mm<sup>2</sup>/s viscosity) or USP isopropyl alcohol is recommended.

From other surfaces: When removing *Dow Corning* MD7-4502 or MD7-4602 Silicone Adhesives from substrates other than skin, *Dow Corning* Q7-9180 Silicone Fluid (1 mm<sup>2</sup>/s viscosity), isopropyl alcohol, ethyl acetate or heptane is recommended. Some of these solvents may cause skin irritation and are highly flammable. They may also deteriorate certain substrates, such as some plastics, and should be used with appropriate precautions.

Note that organic solvents may cause irritation and are flammable; appropriate precautions should be taken. When removing *Dow Corning* MD7-4502 or MD7-4602 Silicone Adhesive from a substrate, and more particularly from skin, apply the appropriate solvent liberally to a clean cloth or gauze pad and wipe the surface clean. Reapplication may be necessary if the residual adhesive layer is heavy.

## Precautions

The solvent carrier (ethyl acetate) in *Dow Corning MD<sup>7</sup>-4502 and MD<sup>7</sup>-4602 Silicone Adhesives* is a flammable liquid with a low flash point (-4.4 °C/24.1 °F), and must be handled with care. Avoid handling the product near open flame or heat sources. Bond or ground containers to prevent static electrical discharge.

- Solvent causes eye irritation; avoid contact with eyes.
- May cause respiratory tract irritation; use with adequate ventilation and keep container closed with not in use. Avoid breathing vapor.
- May be harmful if swallowed; not for internal use.

## HANDLING PRECAUTIONS

PRODUCT SAFETY INFORMATION REQUIRED FOR SAFE USE IS NOT INCLUDED IN THIS DOCUMENT. BEFORE HANDLING, READ PRODUCT AND MATERIAL SAFETY DATA SHEETS AND CONTAINER LABELS FOR SAFE USE, PHYSICAL AND HEALTH HAZARD INFORMATION. THE MATERIAL SAFETY DATA SHEET IS AVAILABLE FROM YOUR DOW CORNING REPRESENTATIVE, OR DISTRIBUTOR, OR BY CALLING YOUR GLOBAL DOW CORNING CONNECTION.

## USABLE LIFE AND STORAGE

When stored at or below 25°C (77°F) in the original, unopened containers, *Dow Corning MD<sup>7</sup>-4502 and MD<sup>7</sup>-4602 Silicone Adhesives* have a shelf life of 72 months from the date of manufacture.

Dow Corning will guarantee the shelf life of these products until the date indicated on the label, if stored in appropriate conditions.

## PACKAGING

*Dow Corning MD<sup>7</sup>-4502 and MD<sup>7</sup>-4602 Silicone Adhesives* are supplied in 16- and 180-kg (35- and 397-lb) containers, net weight.

## SHIPPING LIMITATIONS

*Dow Corning MD<sup>7</sup>-4502 and MD<sup>7</sup>-4602 Silicone Adhesives* contain a flammable solvent. Refer to product packaging and MSDS for additional information.

## HEALTH AND ENVIRONMENTAL INFORMATION

To support customers in their product safety needs, Dow Corning has an extensive Product Stewardship organization and a team of Health, Environment and Regulatory Affairs specialists available in each area. For further information, please consult your local Dow Corning representative.

## ORDERING INFORMATION

To order these products, contact your local Dow Corning Sales Representative or call Dow Corning at +33 (0) 4 92 94 40 00.

Note: Before the first shipment of material, Dow Corning will request that the user signs the PSDS as the confirmation that it has been received, read and understood.

## LIMITED WARRANTY INFORMATION – PLEASE READ CAREFULLY

The information contained herein is offered in good faith and is believed to be accurate. However, because conditions and methods of use of our products are beyond our control, this information should not be used in substitution for customer's tests to ensure that Dow Corning's products are safe, effective, and fully satisfactory for the intended end use. Suggestions of use shall not be taken as inducements to infringe any patent.

Dow Corning's sole warranty is that the product will meet the Dow Corning sales specifications in effect at the time of shipment. Your exclusive remedy for breach of such warranty is limited to refund of purchase price or replacement of any product shown to be other than as warranted.

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